

EXHIBIT A

STATE OF MINNESOTA

DISTRICT COURT

COUNTY OF RAMSEY

SECOND JUDICIAL DISTRICT

CIVIL COURT

In Re: 3M Bair Hugger Litigation

Court File Number: 62-CV-15-6432

ORDER 10

Assigned Judge: William H. Leary III

This matter came before the undersigned Judge of the District Court on May 18, 2017, for a joint hearing before this court and the United States District Court – Minnesota on Plaintiffs' Motion for Leave to Amend Master Long Form and Short Form Complaints to Add Claim for Punitive Damages.

The appearances are those noted at the time of the hearing.

The parties were directed to provide proposed orders by June 1, 2017, after which the matter was taken under advisement.

This court, having in mind the arguments of counsel, the applicable law, and all files and records herein, issues the following order.

IT IS ORDERED that Plaintiffs' Motion for Leave to Amend Master Long Form and Short Form Complaints to Add Claim for Punitive Damages is **DENIED**.

The accompanying memorandum is incorporated herein by reference.

August 18, 2017



William H. Leary III
Judge of District Court

MEMORANDUM

1. Plaintiffs' and Defendants' liaison counsel agreed to submit Plaintiffs' Motion for Leave to Amend Master Long Form and Short Form Complaints to Add Claim for Punitive Damages in a single hearing before a joint session of the United States District Court and the Ramsey County District Court.

2. At the conclusion of the hearing on Plaintiffs' motion, the undersigned directed the parties to submit proposed orders for this court's consideration. The proposed orders were filed on June 1, 2017, at which time the court took the matter under advisement.

3. Each party's proposed order represents the party's view of the evidence and law to be applied. This court has carefully considered the record presented, the arguments of counsel, the applicable law, and the proposed orders. To the extent that this order adopts the analysis and language of a party's proposed order, this court has determined that they accurately reflect the evidence and applicable law.

I. Relevant Legal Standards

4. "Punitive damages are not generally favored by the law." *Lewis v. Equitable Life Assurance Soc'y of the United States*, 389 N.W.2d 876, 892 (Minn. 1986).

5. Minnesota law prohibits a plaintiff from seeking punitive damages unless the plaintiff is first able to satisfy the preliminary evidentiary burden set forth in Minnesota Statute Section 549.191. *McKenzie v. Northern States Power Co.*, 440 N.W.2d 183, 184 (Minn. Ct. App. 1989) (Minn. Stat. § 549.191 "creates a preliminary evidentiary burden which plaintiff must meet before he may plead punitive damages") (quoting *Fournier v. Marigold Foods, Inc.*, 678 F. Supp. 1420, 1422 (D. Minn. 1988)).

6. Thus, the purpose of section 549.191 is to ensure that punitive damages are only pleaded in those cases where such damages are appropriate. *Bougie v. Sibley Manor, Inc.*, 504 N.W.2d 493, 499 (Minn. App. 1993). The statute "serves a fundamental gatekeeping function which rids the courts of unfounded, or of abusive, punitive damage claims." *Backlund v. City of Duluth*, 176 F.R.D. 316, 320 (D. Minn. 1997); see also *Ulrich v. City of Crosby*, 848 F. Supp. 861, 867 (D. Minn. 1994) (Minnesota Statute Section 549.191 was adopted "in order to deter certain practices in the presentment of punitive damage claims which were thought to be abusive"); *Gamma-10 Plastics, Inc. v. Am. President Lines, Ltd.*, 32 F.3d 1244, 1255 (8th Cir. 1994) (policy underlying Minnesota Statute Section 549.191 "was enacted to prevent frivolous punitive damage claims by allowing a court to determine first if punitive damages are appropriate").

A. Plaintiffs' Burden: Clear and Convincing Evidence of Deliberate Disregard of a High Probability of Injury.

7. Under Minnesota substantive punitive damages standard, set forth in Minnesota Statute Section 549.20, a plaintiff must present clear and convincing evidence that a defendant

acted with deliberate disregard of a high probability of injury before the plaintiff can assert a claim for punitive damages:

(a) Punitive damages shall be allowed in civil actions only upon clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others.

(b) A defendant has acted with deliberate disregard for the rights or safety of others if the defendant has knowledge of facts or intentionally disregards facts that create a high probability of injury to the rights or safety of others and:

(1) deliberately proceeds to act in conscious or intentional disregard of the high degree of probability of injury to the rights or safety of others; or

(2) deliberately proceeds to act with indifference to the high probability of injury to the rights or safety of others.

Id.; see also *Bunker v. Meshbesher*, 147 F.3d 691, 696 (8th Cir. 1998) (the “clear and convincing standard of proof is implicitly incorporated” into the requirement that Plaintiffs establish a *prima facie* case of deliberate disregard); *Gamma-10*, 32 F.3d at 1254-55 (“In Minnesota, a plaintiff makes a *prima facie* case for punitive damages by establishing ‘clear and convincing evidence that the acts of the defendant show deliberate disregard for the rights or safety of others.’”); *McKenzie*, 440 N.W.2d at 184 (“[T]he trial court must consider the elements and burden of proof required to recover punitive damages when deciding whether *prima facie* evidence has been submitted and ruling on a motion to amend.”).

8. “[T]he mere existence of negligence or of gross negligence does not rise to the level of willful indifference so as to warrant a claim for punitive damages.” *Ulrich*, 848 F. Supp. at 868 (D. Minn. 1994); see also *Admiral Merchants Motor Freight, Inc. v. O'Connor & Hannan*, 494 N.W.2d 261, 268 (Minn. 1992) (“A mere showing of negligence is not sufficient; instead, the conduct must be done with malicious, willful, or reckless disregard for the rights of others.”); *McCloud v. Norwest Bank Minn., N.A.*, No. C4-96-601, 1996 WL 509846, at *5 (Minn. Ct. App. Sept. 10, 1996) (“Evidence of negligence or gross negligence does not warrant a claim for punitive damages.”); *McKenzie*, 440 N.W.2d at 184 (“mere indifference to others is insufficient and plaintiff must establish maliciousness by intentional or willful failure to act despite knowledge of danger to others”) (citing *Wikert v. Northern Sand & Gravel, Inc.*, 402 N.W.2d 178, 182-83 (Minn. Ct. App. 1987)).

B. The Court Must Focus on the Evidence Presented, Not Plaintiffs’ Allegations or Characterization of the Evidence.

9. When presented with a motion to permit assertion of a punitive damage claim, the function of the trial court is to do more than “rubber stamp” the allegations in the motion papers. *Shetka v. Kueppers, Kueppers, Von Feldt & Salmen*, 454 N.W.2d 916, 918 n.1 (Minn. 1990).

10. In determining whether Plaintiffs have met their burden, the court cannot rely on Plaintiffs' arguments, nor upon Plaintiffs' construction of documents, speculation or conclusory comment. The court must "carefully scrutinize" the evidence apart from Plaintiffs' advocacy. *See id.* at 1011-12 (counsel's construction of documents "'infused with his robust advocacy, as supplemented by a liberal use of surmise, conjecture and conclusory comment" is insufficient to support a motion for leave to assert a punitive damage claim); *Berczyk v. Emerson Tool Co.*, 291 F. Supp. 2d 1004, 1012 n. 7 (D. Minn. 2003) (denying leave to seek punitive damages where "[t]he degree of deviation, between the Affiant's summarization of the referenced documents, and the content of the documents, is frequently considerable."); *Target Corp. v. LCH Pavement Consultants, LLC*, 960 F. Supp. 2d 999 (D. Minn. 2013) ("[T]he Court must carefully scrutinize the evidence presented by the moving party to make sure that it amounts to a prima facie showing that the substantive requirements for punitive damages have been met.").

C. The Court May Consider Only Competent and Relevant Evidence.

11. Not all material submitted by a plaintiff may be considered by the court. A motion for leave to assert a punitive damages claim must be based upon competent, admissible evidence. *Berczyk*, 291 F. Supp. 2d at 1010 ("Quite plainly, a 'prima facie case,' established by 'clear and convincing' evidence, requires evidence that is both competent, and probative, that is, the evidence must be admissible.").

12. Evidence that is circumstantial, or that could be construed as demonstrating "mere indifference" to the plaintiff's rights, is insufficient to satisfy the plaintiff's evidentiary burden and a motion based on such evidence should be denied. *Gamma-10*, 32 F.3d at 1255 (motion to amend denied where plaintiff provided "at best only circumstantial evidence that [defendant] acted recklessly, willfully, deliberately or with gross disregard for [plaintiff's] rights" and where alleged misconduct could have been committed, instead, with mere indifference to plaintiff's rights). Similarly, a claim for punitive damages is inappropriate where the evidence presented allows for the conclusion that the defendant acted in good faith. *Peterson v. Sorlien*, 299 N.W.2d 123, 129 (Minn. 1980) ("Good faith is a proper defense to punitive damages, even though defendants might have been mistaken in their belief that a party was in jeopardy or that their decisions were correct.").

13. The court may not consider unsworn expert reports or statements under Minn. Stat. § 549.191. *Healey v. I-Flow LLC*, 853 F. Supp. 2d 868, 881 (D. Minn. 2012).

14. A plaintiff also may not rely on evidence of alleged misconduct that is unrelated to the underlying claims for relief or that relates to a claim for which punitive damages are inappropriate. *See State Farm Mutual Automobile Ins. Co. v. Campbell*, 538 U.S. 408, 422-23 (2003) (a claim for punitive damages may not be based upon conduct that bears no relationship to the plaintiff's harm); *see also Rosenbloom v. Flygare*, 501 N.W.2d 597, 601 (Minn. 1993) (trial court erred by permitting jury to consider evidence of racial discrimination in awarding punitive damages because such evidence was not relevant to the claim for which punitive damages could be awarded).

D. Limitations on Conduct that May Be Imputed to a Corporation.

15. Minnesota Statute Section 549.20 also strictly limits the conduct that may be imputed to a corporate defendant in determining whether the punitive damages standard has been met. Acts may be imputed only if done by a person “employed in a managerial capacity with authority to establish policy and make planning level decisions” or if a person with such authority “ratified or approved” the statements. Minn. Stat. § 549.20, subd. 2(3), (4). The court cannot consider employee statements as evidence to support Plaintiffs’ *prima facie* showing unless they satisfy the statutory managerial authority test. *See Baufield v. Safelite Glass Corp.*, 829 F. Supp. 285, 286 (D. Minn. 1993) (granting judgment as a matter of law to defendant as to plaintiff’s claim for punitive damages where plaintiff failed to satisfy the statute’s managerial authority test); *DOE YZ v. Shattuck-St. Mary’s School*, No. 15-1151, 2016 WL 5858641, at *22 (D. Minn. Oct. 5, 2016) (denying leave to amend to allege punitive damages: “While [knowledge of nonmanagerial employees] is imputable to [the corporation] for negligence purposes, it is not imputable to [the corporation] for assessing punitive liability.”).

E. The Court May Apply the Evidentiary Rule of Completeness to Provide Context and Guarantee Fairness.

16. While the Court may not consider pure rebuttal evidence in evaluating a motion under Minn. Stat. § 549.19, Minnesota law nonetheless permits, and may even require, the court to consider other relevant portions of the documents or testimony to ensure fundamental fairness. Put another way, the Court is not required to – and should not – consider only the line or page of a document highlighted by Plaintiffs, when the next line or page provides important context. *See Berczyk*, 291 F. Supp. 2d at 1013-14 (finding that “snippets” from various documents “appended” to each other cannot satisfy the plaintiffs’ burden).

17. Furthermore, Rule 106 of the Minnesota Rules of Evidence provides that “[w]hen a writing or recorded statement or part thereof is introduced by a party, an adverse party may require the introduction at that time of any other part or any other writing or recorded statement which ought in fairness to be considered *contemporaneously* with it.” *State v. Robledo-Kinney*, 615 N.W.2d 25, 29 (Minn. 2000) (emphasis added). “The rule is based on concepts of fairness and encourages the trial judge to require the admission of all relevant portions of a document when a party attempts to use selected portions.” 11 Minn. Prac., Evidence § 106.01 (4th ed. 2016). “The rationale is to insure that the offer of evidence is placed in proper context so that the jury is not incurably prejudiced by the use of selective parts of an equivocal document. To wait until the adverse party can introduce the other portions of the document in the adverse party’s case is an inadequate response to the problem.” *Id.*; *see also State v. Brodt*, 150 Minn. 431, 185 N.W. 645, 647 (1921) (“When the significance of a former statement of a witness has been distorted by a fragmentary or inaccurate repetition of it, the entire conversation or writing may be received to explain its true significance”). Thus, this court may consider other excerpts of the same documents and depositions offered by Plaintiffs to ensure that it understands the full context and to guarantee fundamental fairness. This Court’s decision to deny Plaintiffs’ motion still would be the same, however, even if it considered only Plaintiffs’ submissions.

II. Choice of Law

18. The amendment procedure of Minn. Stat. § 549.191 is procedural and applies to all plaintiffs with Bair Hugger lawsuits pending in Ramsey County.

19. The legal standard for recovering punitive damages is substantive, however, and requires a choice-of-law analysis. *See Healey* at 874 (“[I]f the applicable punitive damages law does not allow punitive damages for the type of claim at issue, then of course the plaintiff could not meet section 549.191 requirements because the moving party could not make out a prima facie showing of entitlement to punitive damages.”).

20. While there has been only limited, case-specific discovery to date, the parties concur that Minnesota substantive law is likely to apply to cases brought by Minnesota residents who allege that they developed surgical site infections after a medical procedure that occurred in Minnesota. Based on information presently available to the parties, those cases are as follows:

Case Number	Title	Current State of Residency	Residency at Time of Surgery	Surgery Location
62-cv-15-4748	Sehnert	Minnesota	Minnesota	Minnesota
62-cv-16-3236	Schweim	Minnesota	Minnesota	Minnesota
62-cv-15-6477	Wohl	Minnesota	Minnesota	Minnesota
62-cv-15-7356	Ayotte	Minnesota	Minnesota	Minnesota
62-cv-15-7364	Duquette	Minnesota	Minnesota	Minnesota
62-cv-15-7363	Duvernay	Minnesota	Minnesota	Minnesota
62-cv-15-7362	Enskat	Minnesota	Minnesota	Minnesota
62-cv-16-161	Olson	Minnesota	Minnesota	Minnesota
62-cv-16-547	Rome	Minnesota	Minnesota	Minnesota
62-cv-16-2181	Stevens	Minnesota	Minnesota	Minnesota
62-cv-16-1777	Walker	Minnesota	Minnesota	Minnesota

62-cv-16-3861	Gilmor	Minnesota	Minnesota	Minnesota
62-cv-16-3860	Logan	Minnesota	Unknown	Minnesota
62-cv-16-3950	Pillsbury	Minnesota	Minnesota	Minnesota
62-cv-16-4289	Racine	Minnesota	Minnesota	Minnesota
62-cv-15-6848	Reding	Minnesota	Minnesota	Minnesota
62-cv-17-138	Kelly	Minnesota	Minnesota	Minnesota
62-cv-17-136	Walgren	Minnesota	Minnesota	Minnesota
62-cv-17-727	Foster	Minnesota	Minnesota	Minnesota
62-cv-17-763	Sylvester	Minnesota	Minnesota	Minnesota
62-cv-17-2261	Barber	Minnesota	Minnesota	Minnesota
62-cv-17-2263	Hartman	Minnesota	Minnesota	Minnesota

Because little case-specific discovery has been had at this time, the court does not foreclose the parties from arguing at a later stage of proceedings that a different state's law applies to any of these cases based upon facts subsequently developed.

21. In tort cases involving personal injuries, Minnesota law presumptively does not apply to plaintiffs who are not Minnesota residents and did not receive medical care in Minnesota. *See Schmelzle v. Alza Corp.*, 561 F. Supp. 2d 1046, 1050 (D. Minn. 2008) ("Minnesota's interest in compensating tort victims is lessened where the injury occurred in another state, the injured party is not a Minnesota resident and did not receive medical care here."); *In re Baycol Prods. Litig.*, 218 F.R.D. 197, 207 (D. Minn. 2003) (maintenance of interstate order weighs in favor of applying the law of the state in which the plaintiff resides and where the drug was prescribed). Plaintiffs' motion is limited to an analysis of the substantive standard for recovery of punitive damages under Minnesota law. Plaintiffs have made no attempt to demonstrate that they are entitled to punitive damages under the substantive law of any state other than Minnesota.

III. Plaintiffs' Evidence as to Minn. Stat. § 549.20.

22. Plaintiffs' evidence fails to satisfy their burden to present clear and convincing evidence that either Defendant deliberately disregarded a high probability of injury, as required by Minn. Stat. § 549.20.

A. Plaintiffs' Cited Articles Disclaim Any Conclusion that the Bair Hugger System Causes Surgical Site Infections.

23. As noted one of the studies submitted by Plaintiffs with their motion, forced-air warming, the type of patient warming technology employed by the Bair Hugger system, “is widely used to prevent surgical hypothermia. The benefits of preventing surgical hypothermia include reduced blood loss, improved wound healing, reduced duration of hospital stay, improved survival, and reduced rates of surgical site infections.” (PX38, Reed et al., at 1.¹) *See In re Prempro Prods. Liab. Litig.*, 586 F.3d 547, 572 (8th Cir. 2009) (affirming judgment as a matter of law for Upjohn with respect to punitive damages, despite its violation of federal drug marketing regulations, because “there is no dispute that prescribing [Upjohn’s product] along with estrogen had become the standard of care in hormone replacement therapy”).

24. As noted in another of the studies submitted by Plaintiffs, patient warming is the standard of surgical care: “Patient warming is a recognized and necessary standard of surgical care, with warmed patients having better outcomes through reduced blood loss, improved wound healing, reduced duration of hospital stay, improved survival, and reduced surgical site infection rates for ‘dirty’ (colorectal) surgery.” (PX37, Belani et al., at 1.)

25. Plaintiffs’ core contention is that the Bair Hugger system presents a high probability of injury to patients by causing increased surgical site infections. But Plaintiffs present no evidence that any scientific study – including those studies relied upon by Plaintiffs and their experts – has ever concluded that the Bair Hugger patient warming system causes increased surgical site infections.

26. Plaintiffs cite eight studies published between 2009 and 2013. (Pl. Mem. 24-28.) Nearly all of these studies were either co-authored by an employee of Defendants’ competitor and longtime antagonist, Scott Augustine (Mark Albrecht, listed as a co-author of PX29, PX30, PX33, PX35, PX37, PX38), and/or indicate that they were sponsored by Augustine (PX33 at p. 1544; PX35 at 248; PX37 at p. 5). Even so, not one of these studies concludes that the Bair Hugger system causes surgical site infections. To the contrary, each study expressly disclaims such a conclusion:

Publication	Language Disclaiming Conclusion that Bair Hugger Warming Blanket Increases Risk
Albrecht M et al., Forced-air warming: a source of airborne contamination in the operating room? <i>Orthopedic Rev.</i> 2009; 1(2):e28 (PX29)	“[T]he present study did not evaluate the link between forced air warming and surgical site infection rates ...”
Albrecht M et al., Forced-air warming blowers: An evaluation	“[O]ur findings do not establish a direct link between forced air warming and increased

¹ “PX” refers to exhibits submitted in support of Plaintiffs’ Motion. “DX” refers to exhibits submitted by Defendants.

of filtration adequacy and airborne contamination emissions in the operating room. <i>Am J Infect Control</i> 2010; 39:321-28 (PX30)	surgical site infection rates ...”
McGovern PD et al., Forced-air warming and ultra-clean ventilation do not mix. <i>J Bone & Joint Surg-Br.</i> 2011; 93-B(11):1537-44 (PX33)	“This study does not establish a causal basis for this association [the patient warming device and the risks of surgical site infections in the study].”
Legg A et al., Do forced air patient-warming devices disrupt unidirectional downward airflow? <i>J Bone & Joint Surg-Br.</i> 2012; 94-B:254-6 (PX34) ²	“Because of the nature of our experiment we are unable to conclude that the use of the forced air warming device ... would actually lead to an increased risk of surgical site infection.”
Dasari KR et al., Effect of forced air warming on the performance of operating theatre laminar flow ventilation. <i>Anaesthesia</i> 2012; 67:244-49 (PX35)	“Another limitation of our study is that the definitive effects of this excess heat on clinical outcomes is presently unknown.”
Legg A et al., Forced-air patient warming blankets disrupt unidirectional airflow. <i>Bone Joint J.</i> 2013 Mar; 95-B(3):407-10 (PX36)	“This study does not show that forced-air warming increases the risk of infection ...”
Reed M et al., Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions. <i>AANA J.</i> 2013 Aug; 81(4):275-80 (PX38)	“Last, we did not track hospital infections, nor did we study the association between FAW [forced-air warming] contamination generation/emission and hospital infection rates ...”
Belani K et al., Patient warming excess heat: The effects on orthopedic operating room ventilation performance. <i>Anesthesia & Analgesia</i> 2012 (prepublication on-line) 2013; 117(2):406-411 (PX37)	“Thus, we are unsure of the exact degree of ventilation disruption that might occur in a working OR during orthopedic surgery... future research is warranted to characterize the clinical conditions under which forced air warming excess heat results in ventilation disruption during surgery.”

This is not rebuttal evidence; this is Plaintiffs’ own evidence. In fact, Plaintiffs contend nothing more than that these articles “raised questions” about an increased risk of surgical site infections. (Pl. Proposed Order 16.) Given the articles’ disclaimers, underscored by Plaintiffs’ modest

² Plaintiffs assert that Defendants “attempted to coerce” the *Journal of Bone & Joint Surgery* to retract the 2012 Legg study. (Pl. Mem. 42.) They offer no evidence to support their allegation. Plaintiffs present no evidence that Defendants ever contacted Legg, his co-authors, or the editor.

contention, these studies are not clear and convincing evidence of either a high probability of injury, much less Defendants' deliberate disregard of a high probability of injury.

27. Consistent with the scientific literature, Plaintiffs present no evidence that there has ever been an FDA recall of the Bair Hugger system related to infection (or otherwise). Plaintiffs also present no evidence that the FDA has issued any safety communication, warning letter, or taken any other enforcement action related to an infection. *Compare In re Levaquin Prods. Liab. Litig.*, No. 08-5743, 2010 WL 7852346, at *2 (D. Minn. Nov. 9, 2010) ("several European regulatory authorities decided to take corrective action" based on a series of studies associating levofloxacin use with higher rates of tendon disorders).

28. While it is undisputed that surgeries have been conducted using the Bair Hugger system for more than 25 years, Plaintiffs present no evidence that any doctor has ever reported to 3M or Arizant that the Bair Hugger system caused his or her patient to develop a surgical site infection. The facts here are like those in *Healey*, where the court denied the motion for leave to allege punitive damages. In *Healey*, the plaintiff likewise submitted no evidence that a physician ever informed the defendant that the defendant's medical device had caused his injury. 853 F. Supp. 2d at 877-81. This litigation is also similar to *Mack v. Stryker Corp.*, No. 10-2993 (PAM/JJG), 2012 WL 12896248 (D. Minn. Feb. 28, 2012). There, the court denied leave to amend where there were no reports from doctors of injuries caused by use of Stryker's device prior to the plaintiff's surgery. *Id.* at *4-5.

29. Neither party has identified any case where a court applying Minnesota law has permitted leave to amend to allege punitive damages in similar circumstances: where the defendant's medical device remains the standard of care; its significant benefits to patient health and safety are undisputed; there has been no FDA action or warning; no doctor has complained that the defendant's product caused any injury; and there is no scientific study concluding that the defendant's product causes injuries.

IV. The Arguments in Plaintiffs' Expert Reports Are Not Proof that Defendants Deliberately Disregarded Scientific Proof that the Bair Hugger System Causes Surgical Site Infections.

30. Notwithstanding the disclaimers in the articles relied upon by Plaintiffs, Plaintiffs argue they should be permitted to pursue punitive damages based on the conclusions in reports from two of their retained experts, Drs. Samet and Jarvis. Samet and Jarvis provide causation opinions that the authors of the studies cited by Plaintiffs all declined to reach.

31. As a threshold evidentiary matter, the court may not consider Samet's and Jarvis's reports in determining whether Plaintiffs have met the requirements of Minn. Stat. § 549.191 (which, as explained *supra*, applies regardless of choice of law). As the *Healey* court concluded in refusing to consider plaintiffs' expert reports, an expert report that is not in the form of a sworn affidavit does not satisfy Minn. Stat. § 549.191's requirement that a motion for leave to amend to allege punitive damages be accompanied by affidavits showing the factual basis for the claim. *Healey*, 853 F. Supp. 2d at 881. That the expert reports are attached to the declaration of Plaintiffs' counsel does not make them proper under Minn. Stat. § 549.191.

32. Even if they were procedurally proper, Samet's and Jarvis's reports suffer from the same defect that the plaintiffs' expert reports suffered from in *Healey*. Like Dr. Trippel in *Healey*, Samet and Jarvis did not conduct their own studies, but instead relied upon the same eight studies that Plaintiffs have cited – all of which disclaim the conclusion that the Bair Hugger system causes surgical site infections. *Healey*, 853 F. Supp. 2d at 881-82 (Trippel's review of the medical literature was not clear and convincing evidence). For the purposes of a motion to amend to allege punitive damages, an expert's opinion cannot spin straw into gold – it cannot satisfy the “clear and convincing” standard when the underlying scientific literature does not satisfy that standard. See *Berczyk*, 291 F. Supp. 2d at 1015-16 (expert report submitted in support of punitive damages was “predicated on many of the same documents that we found to be an inadequate basis on which to establish a claim of deliberate disregard”).

33. The problem is illustrated by Samet's conclusions that the McGovern 2011 study demonstrates an “elevated 3.8 risk ratio” and therefore “the Bair Hugger device would constitute a substantial contributing cause” of infections. (PX E at 16.) On its face, the McGovern study does not support this conclusion. The study looked at infection rates at a hospital in the United Kingdom during a period when the Bair Hugger system was in use versus a period when competitor Augustine's HotDog device was in use. McGovern and his co-authors (including Mark Albrecht, an employee of competitor Augustine) noted that their study was not controlled and that several confounding factors could explain the results:

Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational and may be confounded by other infection control measures instituted by the hospital. For example, changes were made to the antibiotic and thromboprophylaxis protocols used during the study, although no infection control changes were made after February 2010.

In addition, we were unable to consider all factors that have been associated with SSI, as the details of blood transfusion, obesity, incontinence and fitness for surgery, which have been identified elsewhere as important predictors for deep infection, were not sufficiently detailed in the medical record.

(PX33 at p. 1543.) Plainly, changes in the antibiotic regimen during the study could be highly relevant to rates of infection.

34. That Samet's and Jarvis's unsworn reports cannot be “clear and convincing” evidence is underscored by another document offered by Plaintiffs. Plaintiffs have submitted excerpts of the 2013 Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection, but have excised portions of the Proceedings that directly undercut their experts' conclusions. (PX4.) As previously discussed, this court may consider other portions of this document under Rule 106 of the Minnesota Rules of Evidence. The Proceedings reflect the “cumulative wisdom of over 400 of the world's experts in musculoskeletal infection from 52 countries.” (DX18 at 4.) The group reached a “strong consensus” in 2013 as follows: “We recognize the theoretical risk posed by FAW [forced air warming] blankets and that no studies

have shown an increase in SSI [surgical site infections] related to the use of these devices. We recommend further study but no change to current practice.” (*Id.* at 5.) Eighty-nine percent of delegates voted in support of the statement while only five percent voted against and six percent disagreed. The discussion and notes indicate that the delegates considered and evaluated the same studies relied upon by Samet and Jarvis, including McGovern. (*Id.*)

35. Defendants’ rejection of a viewpoint supported by just 5 percent of an assembly of more than 400 experts in the field of musculoskeletal infection falls far short of clear and convincing evidence of a deliberate disregard of a high probability of injury.

36. Separately, Plaintiffs also rely upon “testing” in a laboratory clean room by one of their retained experts, Michael Buck, and a computer model created by another of their retained experts, Said Elghobashi. (Pl. Mem. 8-10.) Based on those experts’ conclusions, Plaintiffs argue: “If Defendants had performed proper validation testing prior to marketing the Bair Hugger, they would have found” that air from the Bair Hugger blower increased the amount test particles around the surgical site. (*Id.*) Such an argument is a long way from demonstrating a high probability of injury from an increased rate of infection.

B. Plaintiffs’ Allegation that Arizant and 3M Failed to Validate the Safety of the Bair Hugger System Is Contradicted by Plaintiffs’ Own Evidence.

37. Plaintiffs further argue that Arizant and 3M “failed to validate the safety of the Bair Hugger system” before the Bair Hugger system was used in Plaintiffs’ surgeries. (Pl. Mem. 5.) Plaintiffs cite to several scientific studies focused on the safety of the Bair Hugger system, studies that preceded the use of Bair Hugger systems in most, if not all, of Plaintiffs’ surgeries. (Pl. Mem. 30-32.)

38. First, Plaintiffs concede that in 1993 *Anesthesia & Analgesia* published a study by Zink et al. entitled “Convective warming therapy does not increase the risk of wound contamination in the operating room,” which concluded exactly what the title says. (DX6.) Plaintiffs concede that the study involved Bair Hugger system. This study was published many years before the use of the Bair Hugger system in the surgery of any of the plaintiffs in the MDL.

39. Second, Plaintiffs concede that in 2003 *Critical Care* published a study in which the authors took bacterial cultures at the start and finish of surgery with the use of a Bair Hugger system. (DX7.) The study concluded that “there was no increase in air contamination associated with the Bair Hugger patient warming system.”

40. Third, Plaintiffs concede that in 2009 the *Journal of Hospital Infection* published a study by Moretti et al. in which the authors took cultures with and without the use of the Bair Hugger system. The authors concluded: “Statistical analysis of the results demonstrated that the Bair Hugger system does not pose a real risk for nosocomial infections, whereas it does offer the advantage of preventing the potentially severe consequences of hypothermia during major orthopaedic surgery.” (DX8.)

41. The studies submitted by Plaintiffs also reference other studies supporting the safety of the Bair Hugger system that predate all or most of Plaintiffs’ surgeries. For example,

McGovern and his co-authors cite Kurz et al., “Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization: study of wound infection and temperature group,” published in the *New England Journal of Medicine* in 1996. (PX33 at p. 1544.)

42. Even if Plaintiffs were correct that the Bair Hugger system never went through safety testing prior to their surgeries, that assumption would provide no support for their motion. There is no dispute that the Bair Hugger system is a 510(k) device cleared by the FDA. As the *Healey* court concluded, a medical device manufacturer’s failure to conduct safety and effectiveness testing of a 510(k) device, when the FDA has not required it, is not *prima facie* evidence to support punitive damages. *Healey*, 853 F. Supp. 2d at 879; *see also Mack*, 2012 WL 12896248, at *4 (denying motion for leave to seek punitive damages; Stryker’s failure to conduct safety testing of its pain pump was not clear and convincing evidence because 21 C.F.R. § 807.92 did not require safety and effectiveness testing of the device).

C. Plaintiffs’ Corporate Documents and Deposition Excerpts.

43. The remainder of Plaintiffs’ argument is based heavily on excerpts taken from Arizant and 3M corporate documents generated over a period of nearly 30 years. For the most part, these isolated statements are taken out of context, sometimes with pages missing and relevant attachments omitted. In such circumstances the following holding is instructive:

The Plaintiffs’ Exhibits are a hodge-podge of largely disconnected documents which, like snapshots of different scenes, foreclose any responsible attempt to see the whole. . . . Of course, we are mindful that, with snippets from one document, when appended to another, some apparitions seem vaguely visible, but we must be presented, here, not with nebulous shadows, but with a requisite showing undergirded by clear and convincing evidence.

Berczyk, 291 F. Supp. 2d at 1013-14 (“Plaintiffs would have us read the practical equivalent of ‘tea leaves’ in order to surmise a state of deliberate indifference.”).

44. Moreover, while Plaintiffs label the Arizant and 3M employees who created these documents as “directors” or executives,” it is Plaintiffs’ burden to present actual evidence that each of the individuals whose email and documents they quote³ qualified as a managerial agent of Arizant or 3M with corporate policymaking authority under Minn. Stat. § 549.20, subd. 2(3), or that their conduct was ratified by a managerial agent under Minn. Stat. § 549.20, subd. 2(4).

45. Even without considering any rebuttal evidence, the court finds that Defendants have amply demonstrated that Plaintiffs mischaracterize or take out of context much of the material they have submitted, or have failed to show that the material represents the viewpoints or conduct

³ *See, e.g.*, emails and documents submitted as PX10, PX12, PX14, PX15, PX18, PX19, PX26, PX27, PX28, PX41, PX44, PX45, PX47, PX48, PX49, PX51, PX52, PX53, PX54, PX55, PX57, PX59-67, PX69, PX71, PX72, PX73, PX75, PX76, PX77.

of Defendants' policy-setting managers. (Def. Opp. at 32-40.) Nonetheless, a few of Plaintiffs' contentions warrant further discussion.

46. Plaintiffs argue that Arizant and 3M should have followed through on internal discussions about incorporating a higher-efficiency filter or antimicrobial coating for the blower hose. (Pl. Mem. 15-23.) Plaintiffs, however, fail to present evidence that these discussions were based on acknowledgment of some danger to patients. But even so, evidence that a defendant did or did not explore ways to prevent dangers associated with its product does not satisfy Minnesota's punitive damages standard. *Beniek v. Textron, Inc.*, 479 N.W.2d 719, 721-23 (Minn. App. 1992) (affirming trial court's grant of directed verdict on punitive damages where plaintiff presented evidence that defendant considered adding additional safety features for its chain saws – including patenting one of those features – but did not follow through).

47. Plaintiffs also contend that Arizant and 3M employed “scare-tactics to convince scientists not to publish adverse research.” (Pl. Mem. 36.) Their evidence does not support this allegation.

48. First, in a section entitled “Defendants Willfully Suppressed Potential Harmful Testing,” Plaintiffs assert that an Arizant marketing employee instructed other employees to “poke holes” in an unfavorable article in the *Operating Theatre Journal*. (Pl. Mem. 41.) Plaintiffs' own exhibit makes clear that “unfavorable information” published in the *Operating Theatre Journal* was a paid advertisement by competitor Augustine. (PX72 at 3MBH00002793.) “Poking holes” in a competitor's advertisement is not clear and convincing evidence that Defendants “willfully suppressed potentially harmful testing.”

49. Second, Plaintiffs describe an Arizant employee urging colleagues to make “a vigorous challenge” to certain unspecified findings by physicians at Stanford Medical School. The email Plaintiffs cite suggests how this challenge might be made – by posing such questions to the researchers as, “Did the sampling include adequate controls?” “Why do the authors believe that bacteria within the hose, if present, would be transported to the patient? The mode of transmission for most bacteria is direct touch, not airborne.” “Why do the authors believe that bacteria entrained in the airstream, if present, pose a risk to patients? Other papers, including Avidan, support the safety of BH when used with a blanket.” (PX71 at 3MBH00024680.) Questioning or challenging conclusions based on a contestable study is not proof of “willfully suppress[ing] potentially harmful testing.”

50. Third, Plaintiffs charge 3M with “attempt[ing] to coerce the editor of the *Journal of Bone & Joint Surgery* to retract an adverse study about the Bair Hugger.” (Pl. Mem. 42.) Their sole support for this allegation is an internal email attaching a draft letter to the editor. Bob Buehler writes his colleagues about the draft: “I think you should speak with [then-3M employee] Gary [Hansen] about how a scientist would write such a letter. Also, we should think about it from the point of view of the editor and come up with compelling reasons why not retracting this would cause him pain.” (PX73 at 3MBH0125823.) Plaintiffs offer no evidence that the letter to the editor was ever finalized or sent, or that there were any acts to “coerce” the editor, much less to retract the study.

51. Fourth, Plaintiffs claim that 3M used its influence to kill unfavorable “research” that was to be published in *OR Manager*. (Pl. Mem. 42.) Their sole support for this is an internal email from Gary Hansen in 2010 describing a conversation with Dr. Daniel Sessler of the Cleveland Clinic. Hansen writes: “I spoke to Dan a moment ago. First, the *OR Manager* article will not be published. Dan spoke to the editor and apprised her of the paper’s numerous flaws. It’s dead.” (PX57 at 3MBH00051040.) Plaintiffs offer no evidence to counter Dr. Sessler’s conclusion that the article proposed for publication in *OR Manager* suffered from numerous flaws. They offer no evidence that Dr. Sessler did anything other than communicate his honest scientific viewpoint. They offer no evidence that the editor of *OR Manager* was coerced or intimidated, or that Dr. Sessler used “scare tactics” in the discussion. Plaintiffs do not even describe what this article was about, and present no evidence that it reported on “harmful testing.”

52. Fifth, Plaintiffs assert that following its acquisition of Arizant, 3M “prevented additional testing” by withdrawing the Bair Hugger system from a bundled infection study being performed in the United Kingdom in 2010. Plaintiffs contend that 3M withdrew from the UK study because it was afraid of what the results might show. The single email they cite provides no support for that contention. The email discussed 3M’s objection that the study was using Augustine’s HotDog device “interchangeably with the Bair Hugger and Bair Paws products” and would not ultimately identify any distinction between the effectiveness of the HotDog and the Bair Hugger system. (PX75 at 3MBH00042660.) Plaintiffs offer no evidence that 3M’s objection was invalid or pretextual, much less that its true fear was an adverse result. Nor do Plaintiffs present any evidence that 3M’s objection resulted in the UK study being “suppressed.”

53. Sixth, Plaintiffs assert that Arizant “steered” an organization called ACEP (which Plaintiffs misidentified as “CEDAR”) from testing the safety of the Bair Hugger system. (Pl. Mem. 43.) There is no evidence that ACEP had any plans, intentions, or capability to test the safety of the Bair Hugger system. All Plaintiffs offer in support is a draft response to a 2008 inquiry to Arizant from ACEP concerning a proposed “buyers’ guide” for use by National Health Service purchasers in the United Kingdom. The template asks for a ranking of the importance of “conduct[ing] a physical test of the device to measure an important parameter which will differentiate between more effective devices and less effective devices.” It does not ask about safety testing. The drafter of the response ranks this item behind others in importance because (the drafter wrote), it is “[n]ot necessary. It is difficult to perform such tests validly; tests have already been published.” (PX76 at 3MBH00108247). There is no evidence presented that this draft was finalized in this form or that it was submitted, much less that it “steered” ACEP or anyone else away from testing the safety of the Bair Hugger system.

54. Finally, Plaintiffs allege that 3M stopped the ECRI Institute, a long-established nonprofit organization that advises healthcare organizations, or “steered it away” from conducting its own testing of the safety of the Bair Hugger system. The document Plaintiffs cite (PX77) is not evidence that ECRI ever contemplated doing its own testing, much less that 3M did anything to prevent it. In this internal email (which is not a communication to ECRI), then-3M employee Gary Hansen makes the case that ECRI should not attempt to “duplicate a difficult test that has already been done well, repeatedly, elsewhere.” If ECRI does say that it wishes to conduct testing, he suggests proposing to ECRI that it “conduct a test on only the media (m10 and m20) using the same methodology that we use.” Plaintiffs offer no evidence that 3M proceeded to make either proposal to ECRI.

55. None of this evidence makes out a *prima facie* case of clear and convincing evidence that Defendants “willfully suppressed potentially harmful evidence.” (Pl. Mem. 41.)

V. Conclusion

56. With respect to Bair Hugger cases pending in the Ramsey County District Court, Plaintiffs’ motion is denied. For those cases governed by the substantive law of Minnesota, Plaintiffs have failed to present a *prima facie* claim of clear and convincing evidence that either Arizant or 3M deliberately disregarded a high probability of injury to Plaintiffs. For those cases governed by the substantive law of other states, Plaintiffs have neither articulated the relevant legal standards for establishing their entitlement to punitive damages nor attempted to demonstrate that their evidence satisfies those standards. Accordingly, their motion is also denied with respect to cases as to which Minnesota substantive law does not apply.

WHL